K012917

NOV 2 8 2001

Appendix A (Summary of Safety And Effectiveness)

Submitter:
John Gagliardi, President **(contact person)**
MidWest Process Innovation, LLC
7736 Woodside Court
Maineville, OH 45039
513-573-0085 (Telephone and fax) **or**
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JGAGL777@One.Net

Trade Name: Umbilical Cord Clamp

Common Name: Umbilical Cord Clamp

Classification Name: Umbilical Clamp (21 CFR, Part 884.4530)

Summary of Safety and Effectiveness:
The Dynarex Umbilical Cord Clamp instrument is substantially equivalent in function and intended use to these examples of products presently on the market. Specifically, the Dynarex Umbilical Cord Clamp is exactly similar in functional design, performs the same functions and has the same intended use as these presently distributed devices. The packaging methods and packaging materials are exactly the same, respectively.

The Dynarex Umbilical Cord Clamp is indicated for use to compress the umbilical cord and is not different than the predicate device example, therefore the safety, effectiveness and overall function of this device is assured.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 2 8 2001

Dynacare, Inc.
c/o Mr. John Gagliardi
MidWest Process Innovation, LLC
7736 Woodside Court
MAINEVILLE OH 45039

Re: K012917
Trade/Device Name: Dynarex Umbilical Cord Clamp Models-6833 and 6833-B
Regulation Number: 21 CFR §884.4530
Regulation Name: Obstetric-gynecologic specialized manual instrument
Regulatory Class: II
Product Code: 90 HFW
Dated: August 28, 2001
Received: August 30, 2001

Dear Mr. Gagliardi:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K012917

Device Name: Dynarex Umbilical Cord Clamp

Indications for Use: The Dynarex Umbilical Cord Clamp is a device used to compress the umbilical cord. Federal (USA) law restricts this device to sale by or on the order of a physician.

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K012917

Prescription Use ✓